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10/660,110	09/11/2003	Mark F. Oldham	5010-406	6842

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EXAMINER
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NEGIN, RUSSELL SCOTT

ART UNIT	PAPER NUMBER
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1631

MAIL DATE	DELIVERY MODE
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08/07/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/660,110

Applicant(s)

OLDHAM ET AL.

Examiner

Russell S. Negin

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 04 June 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 20-44 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 20-44 is/are rejected.
- 7) ☒ Claim(s) 23 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Comments***

Applicants' request for reconsideration in the communication filed on 27 May 2007 is acknowledged and the amendments are entered.

Claims 20-44 are pending and examined in the instant Office action.

### ***Claim Objections***

Claim 23 is objected to because of the following informalities:

The phrase on the third line states, "the second configuration such that the based on the second configuration," which contains grammatical inconsistencies.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The following rejection is newly applied:

Claims 20-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 20 recites the limitation "the second type of specific particles," in lines 14-15 which mandates a plurality of different types of particles. This finding is inconsistent

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with the preamble which states, "the measurement of one or more types of specific particles," stating the potential of both a single and plurality of types of particles.

Claim 20 recites the limitation "the specific particles" in line 21. There is insufficient antecedent basis for this limitation in the claim. Since the claim recites one or more types of specific particles, it is unclear to which type of particles "the specific particles" refers.

The term "effective measurement" or "effectively measure" or "effectively represent" in claims 20-26, 28-29, 33-35, 37-38, and 40-41 is a relative term which renders the claim indefinite. The term "effective" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Without a clear standard or criterion, one skilled in the art would not know whether or not a particular measurement is effective.

The term "relatively strong component" in claim 21 is a relative term which renders the claim indefinite. The term "relatively strong component" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Without a clear standard or criterion, one skilled in the art would not know whether or not a particular component is relatively strong.

The term "relatively weak component" in claim 21 is a relative term which renders the claim indefinite. The term "relatively weak component" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and

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one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Without a clear standard or criterion, one skilled in the art would not know whether or not a particular component is relatively weak.

The term "strong component" in claims 23-25, 34, 36-37, and 40 is a relative term which renders the claim indefinite. The term "strong component" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Without a clear standard or criterion, one skilled in the art would not know whether or not a particular component is strong.

The term "weak component" in claims 23-24, 29, 35-36, 38, and 41 is a relative term which renders the claim indefinite. The term "weak component" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Without a clear standard or criterion, one skilled in the art would not know whether or not a particular component is weak.

The term "short exposure duration" in claims 25 and 37 is a relative term which renders the claim indefinite. The term "short exposure duration" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Without a clear standard or criterion, one skilled in the art would not know whether or not a particular exposure duration is short.

The term "long exposure duration" in claims 26 and 37 is a relative term which renders the claim indefinite. The term "long exposure duration" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Without a clear standard or criterion, one skilled in the art would not know whether or not a particular exposure duration is long.

The term "low operating voltage" in claims 28 and 40 is a relative term which renders the claim indefinite. The term "low operating voltage" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Without a clear standard or criterion, one skilled in the art would not know whether or not a particular operating voltage is low.

The term "high operating voltage" in claims 29 and 41 is a relative term which renders the claim indefinite. The term "high operating voltage" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Without a clear standard or criterion, one skilled in the art would not know whether or not a particular operating voltage is high.

### ***Claim Rejections - 35 USC § 102***

The rejections of claims 20-24 and 33-36 under 35 U.S.C. 102(b) as being anticipated by Morris [Nuclear Magnetic Resonance Imaging in Medicine and Biology,

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1986, Oxford: Clarendon Press] are withdrawn in view of amendments made by applicant to the set of claims filed on 4 June 2007.

***Claim Rejections - 35 USC § 103***

The rejections of claims 20-30 and 33-42 under 35 U.S.C. 103(a) as being unpatentable over Morris in view of Churchill et al. [IEEE Transactions on Aerospace and Electronic Systems, Volume AES-17, no. 1, 1981] in view of Pierre et al. [IEEE Transactions on Aerospace and Electronic Systems, 1995 pages 1900-1902] in view of Tacklind et al. [US PG PUB 2003/0101605 A1] are withdrawn in view of amendments made by applicant to the set of claims filed on 4 June 2007.

The rejections of claims 20-24, 28-36, and 40-44 under 35 U.S.C. 103(a) as being unpatentable over Morris in view of Churchill et al. in view of Pierre et al. in view of Tacklind et al. as applied to claims 22-30 and 33-42 above in further view of Photomultiplier Tubes [Hamamatsu Brochure, pages 1-15, July 2002] are withdrawn in view of amendments made by applicant to the set of claims filed on 4 June 2007.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

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were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The following rejection is newly applied:

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tomlinson et al. [Electrophoresis, 1994, volume 15, pages 62-71] in view of Likuski [US Patent 5,932,080 issued 3 August 1999].

Claim 20 is drawn to a method for improving the measurement of one or more types of specific particles of a sample using a photodetector associated with a biological analysis system wherein the specific particles are adapted to emit identifiable signals based in the interaction of the specific particle with corresponding probes and wherein the identifiable signals are captured by the photodetector to yield an output signal and wherein the photodetector is adapted to be operated at different configurations that respond differently to the identifiable signals comprising the following steps:

- performing a first measurement of the signals at a first configuration wherein the first configuration includes a first operating parameter of the photodetector;
- performing a second measurement of the signals at a second configuration wherein the second configuration includes a second operating parameter of the photodetector;
- and



--adjusting one of the first and second output signals based on a relationship between the first and second parameters to obtain a separately scaled representation of at least one of the two identifiable signals wherein the representation of the signals includes generating effective representations of the first and second types of the specific particles to thereby allow improved identification of the specific particles within the sample.

The study of Tomlinson et al. investigates drug metabolism using capillary electrophoresis with photodiode array detection; as is states in the first sentence of the abstract:

The application of capillary electrophoresis (CE) with photodiode array detection (DAD) and on-line CE-mass spectrometry (CE-MS) for analysis of both in vitro and in vivo drug metabolism is generated.

For example, Figures 3 and 4 in Tomlinson et al. illustrate electropherograms of HAL and several standards analyzed by CE and CE equipped with DAD, respectively. Consequently, the electropherograms display a plurality of different types of particles. Photodetectors are used to measure the quantity of particle species as a function of time. Figure 3 and Figure 4 demonstrate two separate configurations of the apparatus (Figure 3 shows CE while Figure 4 shows CE equipped with DAD). Each configuration responds differently to the identifiable signals of the particles as is evidenced by differences in the electropherograms.

While the UV photodetector in Figure 3 in Tomlinson et al. is only capable of performing at a specific wavelength (in this case 214 nm), the DAD photodetector in Figure 4, although set at 214 nm, has a multi-wavelength capability in terms of detection. In addition, the voltage drop in the CE experiment is 30 kV (Figure 3) while it

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is 20 kV in the CE-DAD experiment (Figure 4). Consequently, each configuration operates under its own set of operating parameters in terms of possible wavelengths and voltage drops examined.

While Tomlinson et al. illustrates the plurality of particles, operating parameters, and configurations, Tomlinson et al. does not show a relationship between the first and second parameters to obtain a separately scaled representation of at least one of the two identifiable signals wherein the representation of the identifiable signals includes generating effective representations of the first and second types of particles to thereby allow improved identification of the particles within the sample.

The patent of Likuski teaches the mobility-based, normalized capillary electrophoresis. The abstract of Likuski states:

Identification and quantification of constituents of a sample is achieved by mobility based electropherograms obtained from capillary electrophoresis, the mobilities being normalized by zero correction followed by division by the mobility of a selected marker. Zero correction is achieved either relative to a separate marker or by calculation based on the same marker. The resulting electropherograms are more recognizable since they more closely resemble the scanned separation patterns obtained with planar gels, and individual constituents of the sample are more easily and reliably identified since their positions are more easily and reliably identified since their positions in the electropherogram are substantially constant from one electropherogram to the next and hence reproducible to a high degree of accuracy.

Consequently, equations 1-8 of Likuski teach the normalization, correction and scaling of the electrophoretic mobilities of a compound of interest in terms of a marker that migrates with the electroosmotic flow of the capillary. The equations of Likuski are applicable to both CE and CE-DAD apparatus.

Below is a table showing a one-to-one correspondence between the terms in the instant claim and the concepts in Tomlinson et al. and Likuski:

Term	Representation
First measurement	Electrophoretic mobility of HAL in Tomlinson et al.
Second measurement	Electroosmotic mobilities of markers in Tomlinson et al.
First configuration	CE (Figure 3 of Tomlinson et al.)
Second configuration	CE-DAD (Figure 4 of Tomlinson et al.)
First operating parameter	Separation voltage of 30 kV; single wavelength
Second operating parameter	Separation voltage of 20 kV; multiple wavelength
Scaling relation	Equations 1-8 of Likuski

It would have been obvious to someone of ordinary skill in the art at the time of the instant invention to modify the configurations and measurements of Tomlinson et al. by use of the relations of Likuski because Likuski has the advantage of displaying the mathematical relations necessary for clarity, accuracy, and reproducibility of the mobility data by correcting for electroosmotic flow of neutral markers, and changes in voltage drop across the capillary, and capillary length.

### ***Response to Arguments***

Applicant's arguments filed 4 June 2007 have been fully considered and they are persuasive in light of amendments filed by applicant to the set of claims on 4 June 2007. New ground(s) of rejection are applied.

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**Conclusion**

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the central PTO Fax Center. The faxing of such pages must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Negin, Ph.D., whose telephone number is (571) 272-1083. The examiner can normally be reached on Monday-Friday from 7am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Ram Shukla, Supervisory Patent Examiner, can be reached at (571) 272-0735.

Information regarding the status of the application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information on the PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RSN

31 July 2007



7/31/07

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